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Remarks

The Applicant believes that this amendment places the subject application in better condition for allowance and in so doing introduces no new issues. Therefore, entry of this Amendment, reconsideration of the application, and allowance of all claims pending herein is respectfully requested.

Claims 1-26 were originally presented in the subject application. By the foregoing amendment, the Examiner's noted informalities in the specification have been corrected, and claims 1, 5, and 21 have been amended to more particularly point out and distinctly claim the inventive material of the subject invention. Claims 4, 6-9, 17, 20, and 21 have been amended to accommodate the Examiner's objections. Claims 1-26 remain in this case.

The Examiner's concerns are addressed separately below in the order raised in the outstanding Office Action. No new matter has been added.

Specification and Claim Objections

Each of the objections to the specification noted in the Office Action has been addressed in the specification and claim amendments submitted herewith. Although the Applicant respectfully disagrees with the Examiner's claim objections and concerns about the specification, the appropriate changes have been made to expedite prosecution. No new matter is believed added to the application by any amendment presented herewith.

Rejections under 35 U.S.C. §112

Claims 1, 5 and 21 stand rejected under 35 U.S.C. §112, second paragraph, as not specifically pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Applicant has amended claim 1 to recite "a surface," instead of "the surface" as recited in original claim 1. Applicant has also amended claim 5 to remove the word "the" before the words "strength of." Claim 21 has been amended to change "the production batch" to "a production

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batch" and to change "the date" to "a date." Applicant therefore respectfully submits that these grounds of rejection should be withdrawn.

Rejections under 35 U.S.C. §103:

Claims 1-4, 10-12, 17, 20, 21

Claims 1-4, 10-12, 17, 20, and 21 stand rejected under § 103(a) as being unpatentable over Howard (U.S. Patent No. 5,945,341) in view of Ruppender (U.S. Patent No. 4,510,383). The Office Action states that "Howard fails to teach the gaps and the test fields having relative sizes, which are optically discernable, wherein the relative sizes form a coded sequence that correlates to information relating to the test."

The Office Action also states that "Ruppender teaches an optical identification of a coding, which consists of a distance between a code block and a first adjacent test field of a test strip (column 1, lines 13-18). . . . [T]he distance (gap) between the code field and the first test field . . . can be used as a coding for certain information (column 1, lines 23-25). On the surface of the test strip, there is provided a bar coding which consists of individual code bars, which vary in breadth and in their distance (gap) apart (columns 3, lines 13-15). Parts of carrier material not having any code bars represent gaps (column 3, lines 13-19 and Fig. 1)." (Office Action at 6).

The Examiner concluded that "it would have been obvious to one of ordinary skill in the art at the time of the invention to combine the color coding method using marker field having a capability to reflect light at different specific ranges of wavelengths from each other as taught by Howard with another coding method, which uses varying distances between a code block and a first adjacent test field of a test strip as taught by Ruppender in order to provide an optical identification of the coding for an adjacent test field Thus, the plurality of test fields with . . . adjacent gaps used as coding information provides the arrangement of plurality of test fields disposed in spaced relation to one another on a carrier, wherein the marker fields (gaps) between the test fields exhibit light reflectance within the first predetermined spectral range." (Office Action at ¶ 19, p. 6-7).

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Claims 3, 4, 10-12, 17, 20, and 21 depend from independent claim 2, which recites "test fields disposed in spaced relation . . . to define a series of gaps therebetween; said gaps and said test fields each being configured in one of a plurality of predetermined sizes; said predetermined sizes being disposed to form a coded sequence that correlates to information relating to the test." Independent claim 1 similarly recites "relative sizes [of test fields and gaps therebetween] forming a coded sequence that correlates to information relating to the test."

This claimed characteristic, of sizes of test areas and gaps therebetween being disposed to form a coded sequence that correlates to information relating to the test, is neither taught nor suggested by the cited prior art. Therefore, the rejection of claims 1-4, 10-12, 17, 20, and 21 is respectfully traversed.

It is well established that in order to make out a prima facie case of obviousness, the prior art references must teach or suggest all of the claim limitations. MPEP 2142. The prior art references cited by the examiner do not teach or suggest the embedding of identifying information in the test areas and gaps between the areas, rather than in a separate bar code or code block placed in a different area from the test areas in the test strip.

Howard '341 discloses a test strip with a discrete identifying code block placed apart from the test areas in the test strip. Ruppender similarly discloses bar coding on a diagnostic test strip in an evaluation device which is separate from the test areas. (Ruppender col. 1 lines 51-53). Ruppender does not disclose a bar code made up of test areas and gaps between the test areas.

A prima facie case of obviousness has not been made because the references cited by the Examiner do not teach or suggest the feature of the claimed invention of a coded sequence formed from the sizes of test areas and gaps. Ruppender teaches away from this feature, and the principle of operation of the Howard '341 reference would have to be changed to create the claimed invention. The proposed combination would lead to a test strip having test fields and a discrete bar code, but would not produce the claimed invention in which the test fields and gaps themselves form a coded sequence. The test pads of the claimed invention perform the dual function of analyte test fields and bar code information encoding. This dual functionality is not provided by either of the cited references.

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Moreover, Applicant respectfully notes Ruppender teaches away from the use of a coding consisting of the distance between a code block and a first adjacent test field. (Office Action at 6). The Examiner cites the "Background of the Invention" section of the Ruppender disclosure, where the device of Betts (U.S. No. 3,907,503) is distinguished from the Ruppender invention. (Ruppender col. 13-18, 23-25). Ruppender states that this "known device can certainly be used for reading off very simple information from test strips. However, it would be desirable if more information could be accommodated in the test strip." (Ruppender col. 1 lines 29-32). Ruppender uses a conventional bar code placed separately on the test strip to provide this high density optical coding.

Alternatively, modifying the combined references would require a change in the principle of operation of the inventions disclosed in these references. "If the proposed modification or combination of the prior art would change the principle of operation of the prior art invention being modified, then the teachings of the references are not sufficient to render the claims *prima facie obvious*." MPEP § 2143.02. A principle of operation of Howard '341 is to require identification of the test strip before any analysis of the testing areas may take place. (Howard '341 col. 4 lines 4-16). If the strip can not be identified, the test areas are not analyzed. (Howard '341 Fig. 7). Under the proposed modification, the Howard '341 method would have to be changed so that each test area and gap in between would have to be measured before any analysis of the strip could take place. The Howard '341 device would have to loop through all of the gaps in the test areas in order to identify and calibrate the test strip, then repeat the process of looping through the color bars again. In other words, it would have to read the strip twice.

As discussed above, Ruppender teaches away from Betts' use of the distance of the code block from the test area as a means of encoding information. Instead, Ruppender cites Betts, U.S. No. 3,907,503 as distinguishable art in the "Background of the Invention" section. Betts, like Howard, requires that the test strip be identified at the beginning of the process so that the device can be calibrated. (Betts U.S. No. 3,907,503 col. 8, lines 42-45). Under the proposed modification, the Betts principle of operation would have to be changed so that the reading device would have to read the entire test strip to identify it by decoding the sizes of the test areas

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and gaps, before beginning the analysis process.

For the above stated reasons, applicant respectfully requests reconsideration and allowance of claims 1-4, 10-12, 17, 20 and 21. Dependent claims 3-4, 10-12, 17, 20, and 21 are believed allowable for the same reasons as independent claim 2 from which they depend, as well as for their own additional limitations.

Claims 5-9

The Examiner rejected claims 5-9 under § 103(a) as "unpatentable over Howard [‘341] . . . in view of Ruppender . . . as applied to claim 2 above, and further in view of Kibrick ([US No. 4,901,073] . . .). The Examiner noted that "Howard in view of Ruppender fails to teach a test strip, wherein the strength of a response generated by a test field is proportional to the relative size of the test field." (Office Action at 9). The Examiner further stated that "Kibrick teaches an optical encoding system with series of light reflecting wide rectangles and narrow rectangles alternating with dark (i.e. non-reflecting) wide rectangles and narrow rectangles. Kibrick further teaches that strength (high or low) of signal corresponds to the spatial width of the space being scanned (column 17, lines 9-13 and Fig. 8)." (Office Action at 9)

The Examiner concluded that "it would have been obvious to one having ordinary skill in the art at the time of the invention to realize that gaps having varying widths as taught by Howard in view of Ruppender would generate reflectance signals, which correspond to the spatial widths of the gaps, in order to use the gaps with different widths as coding for certain information." (Office Action at 9).

Applicant respectfully traverses this rejection. It is well established that in order to make out a *prima facie* case of obviousness, the prior art references must teach or suggest all of the claim limitations. MPEP 2142. Kibrick does not teach a coding system where the strength of the signal corresponds to the width of the space being scanned. Instead, Kibrick discloses a bar decoding algorithm where the amount of time a signal is generated for a bar or space (temporal width) corresponds to the spatial width of the bar or space.

Kibrick discloses a means for measuring the widths of spaces and bars in a bar code. "The first step in any bar-code decoding algorithm is to measure the relative widths of all of the

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bars and spaces in the bar-code symbol being scanned." (Kibrick at col. 17, lines 3-5). The widths are measured by the length of time of the corresponding signal. "Since the symbol is presumably being scanned at a reasonably steady rate, if the scanner is sensing a space, the length of time the scanner's signal remains high corresponds to the spatial width of that space. Similarly, if the scanner is sensing a bar, the length of time the scanner's signal remains low corresponds to the width of that bar." (Kibrick at col. 17 lines 9-15).

As Figure 8 demonstrates, the width of the space or bar corresponds to its temporal width, not to the intensity of the signal. "FIG. 8 illustrates this correspondence between the temporal width of the high and low portions of the scanner's signal and the spatial width of the respective spaces and bars of the symbol being scanned." (Kibrick at col. 17, 15-19).

In other words, Kibrick measures the widths of spaces and bars by length of time of the corresponding signal, not by the strength of the signal. Kibrick also does not disclose encoding of information on test strips. Since Kibrick in combination with Howard '341 and Ruppender does not teach or suggest the feature of the strength of a response in proportion to the size of the test field being measured, a *prima facie* case of obviousness has not been made on this ground.

For the above stated reasons, applicants respectfully request reconsideration and allowance of claims 5-9.

Claims 13-16, 18, 19

The Examiner rejected claims 13-16, 18, and 19 as "unpatentable over Howard ['341] . . . in view of Ruppender . . . as applied to claim 11 above, and further in view of Howard et al. (U.S. Patent No. 5,408,535 . . .). The Examiner noted that "Howard in view of Ruppender fails to teach a test strip, wherein the coded sequence is defined by the relative width of test fields." The Examiner also noted that "Howard et al. ['535] teaches a test strip reader, which does not require a test strip with a fixed pad size and fixed spacing between test pad areas and can locate, determine physical extent of each color band and measure spectral reflectance in each color band (column 4, lines 25-26" (Office Action at 10-11).

The Examiner concluded that "it would have been obvious to one of ordinary skill in the

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art to include in the test strip of Howard ['341] in view of Ruppender with test pads (test fields) having different sizes and light reflecting capabilities as taught by Howard et al. ['535] in order to use light reflecting characteristics and different sizes as a coding for certain information concerning identification of the test strip."

Applicant respectfully traverses this rejection. It is well established that in order to make out a *prima facie* case of obviousness, the prior art references must teach or suggest all of the claim limitations. MPEP 2142. The above discussed references do not teach or suggest this feature of predetermined sizes of test areas and gaps disposed to form a coded sequence.

Howard et al. '535 does not teach or suggest a test strip with a coded sequence defined by the relative width of test fields. Howard et al. '535 does not measure the widths of the test areas or the gaps between the test areas. The fact that Howard et al. '535 works on non-standard sized test strips does not mean that the spaces between the test fields would have any significance, much less form a coded sequence. The Howard et al. '535 disclosure does not make any mention of significances of sizes of the test areas or of the gaps in between the test areas.

In short, the above cited references do not teach or suggest a coded sequence comprised of the widths of test areas and widths of gaps between test areas. Therefore, a *prima facie* case of obviousness has not been made.

For the above stated reasons, applicants respectfully request reconsideration and allowance of claims 13-16, 18, and 19. Dependent claims 13-16, 18, and 19 are believed allowable for the same reasons as independent claim 2 from which they depend, as well as for their own additional limitations.

Other Matters

A new Oath/Declaration has been submitted with this amendment.

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CONCLUSION

Applicants submit that the dependent claims are allowable for the same reasons as the independent claims from which they directly or ultimately depend, as well as for their additional limitations. Applicant therefore further submits that all of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot.

This application is now believed to be in condition for allowance, and such action at an early date is respectfully requested. However, if any matters remain unresolved, the Examiner is encouraged to contact the undersigned by telephone.

In the unlikely event that the transmittal letter is separated from this document and the Patent Office determines that an extension and/or other relief is required, applicant petitions for any required relief including extensions of time and authorizes the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to **Deposit Account No. 50-0734** referencing docket no. 17050/1098.007. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

Respectfully submitted,



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